UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,646	09/24/2003	Robert J. Steffan	WYNC-0809 (AM100977)	6797

38791 7590 05/05/2006

WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER	
ANDERSON, REBECCA L	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,646	STEFFAN ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *7-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☒ Claim(s) *1-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/03, 4/04, 6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are currently pending in the instant application. Claims 7-16 have been withdrawn from consideration as being for non-elected subject matter, claims 1-6 are objected, and claims 1-6 are rejected.

Election/Restrictions

Applicant's election with traverse of Group I and the further election of the compound of example 64, 4-[1-allyl-7-trifluoromethyl)-1H-indazol-3-yl]benzene-1,3-diol, in the reply filed on 13 February is acknowledged. The traversal is on the ground(s) that there is no serious burden for searching the entire set of claims. This is not found persuasive because the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

While applicant states on page 27 that the election of a specific compound is being made to aid the Examiner in conducting a search and examination of the claimed subject matter, and it is not to be construed as limiting the scope of Applicants' claims and that if the elected subject matter is found to be allowable over the prior art, the search and examination will be expanded to cover the full scope of the claims, it is noted that on pages 3 and 4 of the restriction requirement, it was explained that

> "upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing

> the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses. Examination will then process on the elected compound AND the entire scope of the invention encompassing the elected compound. A clear statement of the examined invention will be set forth in the first action on the merits."

Therefore, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination** is:

The products of the **formulae I** or **II** wherein:

R10, **R11**, **R12** and **n** are as found in claim 1;

R1 is hydrogen, alkyl of 1-6 carbon atoms, alkenyl of 2-7 carbon atoms, cycloalkyl of 3-8 carbon atoms, cycloalkenyl of 4-8 carbon atoms, aryl of 6-20 carbon atoms, or arylalkyl of 7-26 carbon atoms;

R2, **R3**, **R4**, and **R5** are each, independently, hydrogen, alkyl of 1-6 carbon atoms, alkenyl of 2-7 carbon atoms, hydroxyl, alkoxy of 1-6 carbon atoms, aryloxy of 6-20 carbon atoms, halogen, trifluoromethyl, -CN, -NO2, -CHO, or –CO2R11; and

R6, **R7**, **R8** and **R9** are each, independently, hydrogen, alkyl of 1-6 carbon atoms, alkenyl of 2-7 carbon atoms, hydroxyl, alkoxy of 1-6 carbon atoms, aryloxy of 6-20 carbon atoms, halogen, trifluoromethyl, -CO2R11, aryl of 6-20 carbon atoms, or arylalkyl of 7-26 carbon atoms;

or a pharmaceutically acceptable salt thereof.

The remaining subject matter of claims 1-6 that is not drawn to the above elected invention and the subject matter of claims 7-16 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining compounds which are

not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims are, for example, the compounds of the formula (I) or (II) wherein R1 is a saturated, unsaturated, or partially unsaturated heterocyclic ring or ring system of 4-14 atoms, containing 1-4 heteroatoms selected from N, O, and S; or R6, R7, R8 and R9 are a saturated, unsaturated, or partially unsaturated heterocyclic ring or ring system of 4-14 atoms, containing 1-4 heteroatoms selected from N, O, and S wherein the nitrogen or sulfur atoms are optionally oxidized and nitrogen is optionally quaternized, etc

The above mentioned withdrawn compounds which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention, such as by furanyl, thienyl, piperidinyl, piperazinyl, and oxazole, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 549 subclass (200)+ furanyl, class 549 subclass (1)+ thienyl,, class 548 subclass (215)+ oxazole, class 544 subclass 358(+) piperazinyl, etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefor withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper.

Claim Objections

Claims 1-6 are objected to as containing non-elected subject matter. Claims 1-6 presented drawn solely to the elected invention identified supra as: **the elected invention for search and examination**, would overcome this objection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6 directed to an invention not patentably distinct from claims 1-7, 9-11, 18, 19, 22-24, 26, 31, 32 and 50 of commonly assigned US Patent Application 11/194263 (US Pre-Grant Publication 20060030612). Specifically, the conflicting claims claim compounds which generically encompass applicants' instantly claimed elected invention or positional isomers of applicants' instantly claimed elected invention and provide preferences towards applicants' instantly claimed invention or positional isomers thereof and also provide compounds which anticipate applicants' instantly claimed invention and provide specific compounds which are positional isomers of applicants instantly claimed invention.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent No. 11/194263 discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the

conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-7, 9-11, 18, 19, 22-24, 26, 31, 32 and 50 of copending US Patent Application 11/194263 (US Pre-Grant Publication 20060030612). Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims disclose compounds which generically encompass applicants' instantly claimed elected invention or positional isomers thereof, for example, wherein in the conflicting claims R1 is CF3 and R2 is phenyl substituted with O-C(O)R7 or ortho or meta hydroxyl (see conflicting claims 1-7, 9-11, 18, 19, 22-24, 26 and 31)which corresponds to applicants' instant invention wherein R1 is arylalkyl, R9 is trifluoromethyl, R6-R8 are each hydrogen and the position equivalent to R4 is OH, i.e. meta instead of para or OR10 is OCOR11 wherein R11 is alkyl. The conflicting claims furthermore provide pharmaceutical compositions (see claim 50). Furthermore, specific compounds which anticipate

applicants' instant invention are found in conflicting claim 32, see compound xj) 3-[2-benzyl-7-(trifluoromethyl)-2H-indazol-3-yl]phenyl acetate. Also, conflicting claim 32 claims specific positional isomers of applicants' instantly claimed invention, see compounds ad) and cd); 2-(2-benzyl-7-trifluoromethyl-2-H-indazol-3-yl)-phenol and 3-(2-benzyl-7-trifluoromethyl-2-H-indazol-3-yl)-phenol. Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950). Therefore, since the conflicting claims of US Patent Application No. 11/194263 claim compounds which generically overlap with applicants' instantly claimed elected invention, provide preferences towards applicants' instantly claimed elected invention and also provide specific compounds which either anticipate applicants' instantly claimed elected invention or are positional isomers of applicants' instantly claimed elected invention, the claims 1 and 6 are therefore rejected under obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by US Pre-Grant Publication 2002103229. US Pre-Grant Publication 2002103229 discloses the compound of formula (I), page 3, compositions of formula (I), page 13 and

the specific compound of example 2, page 15, (3-(4-hydroxyphenyl)-1H-indazole which corresponds to applicants instant invention wherein R6-R9 are each hydrogen; R1 is hydrogen, R2-R5 are hydrogen and R10 is hydrogen, see compound c) of claim 5: 4-(1H-indazol-3-yl)phenol.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Stadlbauer. Stadlbauer discloses the compound of the formula 32, wherein R1 is methyl which corresponds to applicant's instant invention of formula I wherein R2 is hydroxyl, R3, R4 and R5 are hydrogen, R10 is hydrogen, R1 is alkyl of 1-6 carbon atoms, R6, R7 and R9 are hydrogen and R8 is hydroxyl.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Registry No. 328279-69-2. Registry No. 328279-69-2 is 4-[[3-(4-hydroxyphenyl)-1H-indazol-1-yl]methyl]-phenol which corresponds to applicants' instant invention wherein the compound is a compound of formula I wherein R1 is arylalkyl of 7-26 carbon atoms (see page 6 of the specification wherein the term "arylalkyl" includes substituents, such as hydroxyl); R6-R9 are each hydrogen, R2-R5 are each hydrogen and R10 is hydrogen.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 01180878 (abstract). JP 01180878 discloses the compounds of the formula 2,6-bis(1,1-dimethylethyl-4-(1H-indazol-3-yl)-phenol; 2,6-bis (1,1-dimethylethyl)-4-(1-methyl-1H-indazol-3-yl)-phenol; 2,6-(1,1-dimethylethyl)-4-(1-phenyl-1H-indazol-3-yl)-phenol; 2,6-bis(1,1-diemthylethyl)-4-(1,5-dimethyl-1H-indazol-3-yl)-phenol; and 4-(5-chloro-1-methyl-1H-indazol-3-yl)-2,6-bis(1,1-dimethylethyl)-phenol. JP 01180878 also discloses

that the compounds of the formula I are useful as anti-inflammatories, analgesics, antipyretics, antiallergy agents, antiarthritics, antirheumatics, and blood platelet aggregation inhibitors.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Krishnan et al. Krishnan et al. discloses the compounds: 6 (scheme III, page 448 and table 2, page 449); 7a (scheme IV, page 448); 7 (scheme IV, page 448 and table 2, page 449); and compound 9 (scheme IV, page 448 and table 2, page 449). These compounds correspond to applicants invention of formula I and II wherein R2 is hydroxyl, R3, R4 and R5 are hydrogen, R10 is hydrogen, R1 is hydrogen, alkyl of 1-6 carbon atoms or aryl of 6-20 carbon atoms, R6, R7 and R9 are hydrogen and R8 is hydroxyl.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Shutske et al. Shutske et al. discloses, for example, the intermediate compounds of formula 7a and 7b (see scheme I page 1308 and Table II, page 1309) which correspond to applicants instant invention of formula I wherein R6-R9 are hydrogen; R1 is hydrogen or alkyl of 1-6 carbon atoms; R10 is hydrogen; R2 and R3 are each halogen and R4 and R5 are each hydrogen.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5 and 6 rejected under 35 U.S.C. 102(e) as being anticipated by US Pre-Grant Publication 2002103229. US Pre-Grant Publication 2002103229 discloses

the compound of formula (I), page 3, compositions of formula (I), page 13 and the specific compound of example 2, page 15, (3-(4-hydroxyphenyl)-1H-indazole which corresponds to applicants instant invention wherein R6-R9 are each hydrogen; R1 is hydrogen, R2-R5 are hydrogen and R10 is hydrogen, see compound c) of claim 5: 4-(1H-indazol-3-yl)phenol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01180878 (abstract).

Determining the scope and contents of the prior art

JP 01180878 discloses the compounds of the formula 2,6-bis(1,1-dimethylethyl-4-(1H-indazol-3-yl)-phenol; 2,6-bis (1,1-dimethylethyl)-4-(1-methyl-1H-indazol-3-yl)-phenol; 2,6-(1,1-dimethylethyl)-4-(1-phenyl-1H-indazol-3-yl)-phenol; 2,6-bis(1,1-diemthylethyl)-4-(1,5-dimethyl-1H-indazol-3-yl)-phenol; and 4-(5-chloro-1-methyl-1H-indazol-3-yl)-2,6-bis(1,1-dimethylethyl)-phenol. JP 01180878 also discloses that the compounds of the formula I are useful as anti-inflammatories, analgesics, antipyretics, antiallergy agents, antiarthritics, antirheumatics, and blood platelet aggregation inhibitors.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the claims at issue is that the prior art discloses compounds which are either positional isomers of the claimed invention or differ by a hydrogen instead of a methyl.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art to prepare applicants instantly claimed invention wherein R9 is alkyl of 1-6 carbon atoms or halogen as the prior art discloses compounds which are positional isomers of the claimed invention or differ by a hydrogen instead of a

methyl. It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lohr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (ie., as anti-inflammatories, analgesics, antipyretics, antiallergy agents, antiarthritics, antirheumatics, and blood platelet aggregation inhibitors). In addition nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by JP 01180878, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600
5/1/06

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600